DEPARTMENT OF HEALTH & HUMAN SERVICES

John E Klemmer, C.O.

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10-15-99
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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-03

October 14, 1999

Mr. Fred Geissler, CEO
Grand View Hospital
N 10561 Grand View Lane
Ironwood, MI 49938

Dear Mr. Geissler:

We are writing you because on October 4, 1999, your facility was inspected by a representative of the State of Michigan, acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following level 1 findings at your facility:

1. There was no documentation for processor quality control measurements for [redacted] out of 22 days of operation during the month of June, 1999. This represents a [redacted]% missing record rate for that month.

2. Mammography phantom image QC records were missing for 12 weeks for the [redacted] mammography system.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited

to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These level 2 findings are:

1. Processor QC records were deficient in that there was a failure to document corrective actions when QC measurements showed processor failures for control limits.

2. Mammograms were processed on at least four (4) days when the processor was measured to be out of limits.

3. Processor QC records were observed to be missing for four (4) consecutive days.

4. There was no formal designation of a Lead Interpreting Physician to oversee and ensure that the quality assurance program meets all of the requirements of the MQSA.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U.S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at http://www.fda.gov.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s